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New Requirements for Irradiated Food

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

TH0075: The new regulations for irradiated foods has been prepared and notified to WTO (G/SPS/N/THA/144/Rev.1). U.S. exporter intending to export irradiated foods must provide the certificate of the establishment for irradiation processing as per criteria set forth in the notification. A draft MOPH notification has been provided in this report.

General Information:

New Requirements for Irradiated Food Import to Thailand

On April 26, the Thai Food and Drug Administration under the Ministry of Public Health notified the WTO (G/SPS/N/THA/144/Rev.1) regarding the proposed draft of the Ministry of Public Health (MOPH) notification entitled “Irradiated Foods”. The purpose of this draft is to revise the MOPH notification no. 297 B.E. 2549 (2006) entitled “Irradiated Foods”, notified as G/SPS/N/THA/144 dated April 11, 2006. The proposed draft notification will incorporate the draft MOPH notification on “Method, Equipments for Food Storage of Irradiated Food” notified as G/SPS/N/THA/174 dated December 3, 2008 as Annex1 of the revised notification.

The Ministry of Public Health Notification No. 297 B.E. 2549 (2006) RE: Irradiated Food will be repealed and replaced by the proposed draft MOPH notification as attached. The major revision of the MOPH notification on “Irradiated Food” is to incorporate the section that require food radiation processors to carry out food irradiation processing in accordance with the requirements prescribed in the Annex 1 of the draft MOPH notification (Annex 1, Method and Equipments for Irradiation and Storage of Irradiated Food)

The major revisions in the proposed draft notification are:

- The labeling of irradiated food must display the symbol of food irradiation as appeared in Annex 3 of the proposed notification.
- The criterion set for method and equipment for irradiation and storage of irradiated foods.
- Importers intending to import irradiated foods must provide the certificate of the establishment for irradiation processing as per criteria prescribed in Annex 1 of the attached proposed draft MOPH notification or the equivalent standard from the government authorities or other accepted by the government of the origin countries.

At present, we are not aware of U.S. irradiated foods being imported into Thailand. However, potential exporters will need to provide a certificate from the food radiation processor indicating that their standard conforms to the requirements in this notification, or an equivalent standard from government agency from the exporting countries, or other third party accredited by the government of those exporting countries. This notification will be effective on the date after its publication in the Royal Gazette.

(unofficial translation)

(DRAFT)

NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH

Re: Irradiated Food

It deems appropriate to revise the Notification of the Ministry of Public Health Re:
Irradiated Food

By virtue of the provision of Section 5, 6 (1), and (10) of the Food Act (B.E. 2522 (1979), which restricts personal rights and liberties in conjunction with sections 29, 33, 41, 43 and 45 of the Constitution of the Kingdom of Thailand, the Minister of Public Health, advised by the Food Committee, issues the notification as follows:

Clause 1 Notification of the Ministry of Public Health No. 297 B.E. 2549 (2006) entitled: Irradiated Food, dated 7 August 2549 (2006) shall be repealed. __

Clause 2 In this Notification:

“Irradiated food” means foods processed by ionizing radiation in order to achieve the purpose of irradiation.

“Food irradiation” means processing of food by ionizing radiation to achieve the purpose of the irradiation.

“Food radiation processor” means one who has been granted an approval for processing of food irradiation.

“Absorbed Dose” means the amount of energy absorbed per unit mass of irradiated food product having unit in Grey.

Clause 3 Irradiated food is the prescribed food on methods and equipments for irradiation as well as the storage and labeling of irradiated foods.

Clause 4 Food products intended for radiation process shall be:

(1) Prepared and operated under Good Manufacturing Practices in compliance with the Notification of the Ministry of Public Health entitled “Production Processes, Production

Equipments, and Food Storages” or “Minimum Requirement on Food Hygiene” or “General Principles of Food Hygiene” depending on case in order to achieve the goal of food safety control.

(2) In compliance with the related the Notifications of the Ministry of Public Health on Food.

Clause 5 Packages used for containing irradiated food, either of pre-irradiation or post-irradiation, shall be appropriate and hygienic according to the technological purpose of irradiation as well as to the Notification of the Ministry of Public Health regulations on “Food Packaging”

Clause 6 Irradiation of food shall not be used as a substitute as specified in clause 4

Clause 7 Food irradiation processors are required to practice following the requirements not lower than the criteria as prescribed in Annex 1 of the proposed draft regulation.

Inspection of methods and equipments for irradiation, including the storage of irradiated food shall follow the criteria and conditions as prescribed by the Food and Drug Administration under an approval of the Food Committee

Clause 8 The sources of ionizing radiation shall be as follows;

- (a) Gamma rays from radionuclides Cobalt-60 (^{60}Co) or Cesium -137 (^{137}Cs); or
- (b) X-rays generated from machine sources operated at or below an energy level of 5 MeV; or
- (c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

Clause 9 Absorbed dose for food irradiation shall meet:

- (1) the minimum absorbed dose which is sufficient to achieve the technological purpose of irradiation and,
- (2) the maximum absorbed dose in accordance with the technological purpose of irradiation, but not exceeding the absorbed dose indicated in Annex 2 of the proposed draft regulation which can still retain the nutrition value; not affect its structural integrity, functional properties and sensory attributes.

For the non-comply food irradiation as indicated in Annex 2 of the proposed draft regulation, a supportive technical evidence or reason is required to be shown for the permission by the Food and Drug Administration under an approval of the Food Committee.

Clause 10 Food irradiated shall not be re-irradiated except for foods with low moisture content intended to control the insect reinfestation, such as cereals, pulses, dehydrated foods and other such commodities.

Clause 11 Food is not considered as having been re-irradiated when:

(1) Food was prepared from materials which had been irradiated at low dose levels e.g. quarantine pest control, prevention of sprouting of roots and tubers; and is re-irradiated for the other purposes;

(2) Food, containing less than 5% of irradiated ingredient, is irradiated;

(3) The full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one increment as part of processing for a specific technological purpose.

Clause 12 Irradiated foods in clause 10 and clause 11 shall have cumulative maximum absorbed dose delivered to a food not exceed 10 kGy except when it is necessary to achieve a legitimate technological purpose, and shall not compromise consumer safety or wholesomeness of the food; in this regard, if cumulative maximum absorbed dose exceeds 10 kGy must have a permission from the Food and Drug Administration under an approval of the Food Committee.

Clause 13 Labeling of irradiated foods shall display the following additional details, other than follows the Notification of Ministry of Public Health, Re: Label and Notification of the Ministry of Public Health for each particular food:

(1) Name and location of head office of food manufacturers and food radiation processor;

(2) The word of “ผ่านการฉายรังสีแล้ว” (“irradiated”) or other words that convey the same meaning;

(3) The purpose of irradiation with the following clause “เพื่อ.....” (“For.....”) (specify the purpose of irradiation in the blank)

(4) The food irradiation symbol as appeared in Annex 3 of this Notification in close proximity to the name of the food.

(5) Date, month and year of irradiation.

Clause 14 In case an irradiated food is used as an ingredient in another food or a single ingredient product is prepared from a raw material which has been irradiated. it shall be expressed as clause13(2) accompanied with the name of ingredient.

Clause 15 The transitional period for food irradiation processors of which the permission

approved prior to the effectiveness of this notification, shall follow as stipulated in Clause 7 within one year as from the date of this notification is effective.

Clause 16 Importers are required to provide with the certificate of the establishment for irradiation processing for the imported irradiated food into Thailand not lower than the related criteria as prescribed in Annex 1 or the equivalent standard from the government authorities or others accepted by the government of the origin countries

In case where the reason or necessity to protect the consumers is needed; the Food and Drug Administration may prescribe the establishments as indicated above to achieve the assessment conducted by either the Food and Drug Administration or organizations or authorities announced by the Food and Drugs Administration prescribed under an approval of the Food Committee

Clause 17 Licensees of Import of irradiated food which the license approved prior to the effectiveness of this notification, shall follow as stipulated in clause 16 within one year as from the date of this notification is effective.

Clause 18 Irradiated food manufacturers or importers, whose permissions were granted by the Food and Drug Administration before the effectiveness of this Notification, and the labels did not comply with the clause 13, they shall improve the labeling to conform to this Notification. The transitional period for the labels requirements is allowed to be used but not exceeding to one year as from the date of this notification is effective.

Clause 19 This Notification will be effective on the date after its publication in the Royal Gazette.

Notified on

Annex 1

Attachment to the Notification of the Ministry of Public Health Re: Irradiated Food
Method and Equipments for Irradiation and Storage of Irradiated Food shall be set for irradiation of food as the followings :

| No | Item | Description |
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|----|------|-------------|

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| 1 | Location, building and its design | <p>1.1 Location, building and surrounding area shall be located in area which is appropriate for preventing contamination on irradiated food</p> <p>1.2 Irradiation building design :</p> <p>1.2.1 shall be approved by the responsible government agency on the safety aspects.</p> <p>1.2.2 shall be suitable and have adequate size and space partition.</p> <p>1.2.3 shall be easy for maintenance, cleaning, and convenient to work.</p> <p>1.2.4 shall have sufficient light for operation.</p> <p>1.2.5 shall be enough ventilation for operation.</p> <p>1.2.6 shall have preventive measures to prevent animals and insects to get into the irradiation area.</p> <p>1.3 Inside area of irradiation building shall have rooms or areas as the followings :</p> <p>1.3.1 Rooms or areas for storage non-irradiated foods under appropriated temperature condition.</p> <p>1.3.2 Rooms or areas for storage irradiated foods under appropriated temperature condition.</p> <p>1.3.3 Rooms or areas to locate irradiator and irradiation facilities</p> <p>1.3.4 Irradiation room.</p> <p>1.3.5 These rooms or areas shall be proportionately separated for each line product of irradiation operation.</p> <p>1.3.6 These rooms or areas shall be separated from office restrooms and accommodation for staff to prevent cross contamination.</p> <p>1.3.7 No non-use or irrelevant materials for production in production areas.</p> |
| 2 | Radiation source and facilities | <p>2.1 The following sources of ionizing radiation may be used in food irradiation:</p> <p>2.1.1 Gamma rays from radionuclide Cobalt-60 (^{60}Co) or Cesium-137 (^{137}Cs).</p> <p>2.1.2 X-rays generated from machine sources operated at or below an energy level of 5MeV.</p> <p>2.1.3 Electrons generated from machine sources operated at or below an energy level of 10MeV.</p> |

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| | | <p>2.2 Radiation facilities shall be designed to provide an absorbed dose in the food product within minimum and maximum limits in accordance with process specifications and regulatory requirements.</p> |
| 3 | Food irradiation and operation control | <p>3.1 Foods intended for irradiation process shall be prepared under Good Manufacturing Practices in compliance with the MOPH notifications entitled “Production Processes, Production Equipments, and Food Storages” or “Minimum requirement on food hygiene” or “General Principles of Food Hygiene”</p> <p>3.2 Transportation and storage of the food product prior to irradiation shall have preventive measures to prevent contamination.</p> <p>3.3 The size and shape of packaging used for irradiation shall be designed appropriately with characteristics of food and characteristics of irradiation facilities.</p> <p>3.4 Irradiation of food shall be carried out as the followings :</p> <p>3.4.1 Establish a clear statement for the purpose of irradiation for the irradiation process.</p> <p>3.4.2 Estimate the dose range to achieve the purpose of irradiation which appropriated with the food product intended for irradiation.</p> <p>3.4.3 Test a plant commissioning for first operation and whenever there is a change in radiation source.</p> <p>3.4.4 Test a dose mapping for a particular food product or group of food products for first irradiation and whenever there is a change in loading configuration, weight, density, packaging of foods and radiation source.</p> <p>3.4.5 Control and record all parameters that influence on absorbed dose, such as: radiation source type, strength, time, absorbed dose, order of loading configuration, food product density to ensure that the intended purpose of irradiation is achieved throughout the production lot.</p> <p>3.5 Product Identification :</p> |

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| | | <p>3.5.1 Give a code number to identify the packages at each step in its path through the irradiation process.</p> <p>3.5.2 Record all relevant parameters such as date, time, strength of radiation source, minimum and maximum absorbed dose, temperature, etc of the code number of product, relevant parameters</p> <p>3.6 Post-Irradiation Handling :</p> <p>3.6.1 Shall be appropriate system to separate irradiated foods from non-irradiated foods.</p> <p>3.6.2 Shall be appropriate inspection and storage of irradiated foods as well as the packaging of irradiated food must be complete appearance.</p> <p>3.6.3 Shall be adequate control product and inventory control system to ensure that specific consignments of food products be traced back both to the irradiation facility and the food manufactory of food which intended for irradiation.</p> <p>3.6.4 Shall be appropriate transportation procedures to prevent contamination for irradiated food.</p> |
| 4 | Dosimetry and control | <p>4.1 Select an appropriate dosimetry system, which consists of dosimeters, measurement instruments and their associated reference standards. There shall have procedures for the system's use.</p> <p>4.2 Carry out measurement of a dose distribution.</p> <p>4.3 Carry out measurement of the absorbed dose of food product in the production lot.</p> <p>4.4 Plan and calibration of dosimetry system for radiation processing shall be traceable to national or international standards at least once a year.</p> |
| 5 | Record and report | <p>Food radiation processors shall maintain adequate records of irradiation and keep that records in the irradiation establishment for at least 3 years with good record keeping system.</p> <p>5.1 Product records :</p> <p>5.1.1 Weight, food density, and amount of products that intended for the irradiation process in each production lot.</p> |

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| | | <p>5.1.2 Type of packaging materials used for irradiation.</p> <p>5.1.3 Name and address of food manufacturers.</p> <p>5.1.4 Product code number or lot number</p> <p>5.2 Records of irradiation information and parameters affected on irradiation process. :</p> <p>5.2.1 Strength of radiation source</p> <p>5.2.2 Type of irradiation source, dose range intended to use, and the arrangement of products in the package.</p> <p>5.2.3 Date of irradiation and purpose of irradiation</p> <p>5.2.4 Minimum and maximum absorbed dose including type of domisitors</p> <p>5.2.5 Details of dosimetry system calibration</p> <p>5.2.6 The position of domisitors, radiation dose, and dosimetry results.</p> <p>5.2.7 Results of test samples to confirm the position of domisitors on food products.</p> <p>5.2.8 Method (including instruments and frequency of measurement) for dosimetry process and validation tests.</p> <p>5.3 Reports of dosimetry result.</p> <p>5.4 Records of machine and equipment maintenance system.</p> <p>5.5 Records or reports of staffs' trainings</p> <p>5.6 Records of transportation and their conditions</p> <p>5.7 Records of all relevant documents verification.</p> |
| 6 | Sanitation | <p>6.1 Water to be used for general cleaning in irradiation establishment shall be clean and adjusted quality, if necessary.</p> <p>6.2 Providing appropriate and effective drainage to prevent cross contamination into irradiation process.</p> <p>6.3 Providing appropriate garage bin with lids and appropriate method of elimination system.</p> <p>6.4 Providing adequate and sanitary toilets, hand wash basin for staff with fully facilities to wash hand.</p> <p>6.5 Providing appropriate preventive measurement to eliminate animals and insects in irradiation area.</p> |

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| 7 | Cleaning and maintenance | <p>7.1 Irradiation establishment shall be clean and kept clean at all time.</p> <p>7.2 Tools, equipments, irradiation facilities used for irradiation process, surface area of tools and equipments contact with packaging shall be clean, maintaining, and kept clean.</p> <p>7.3 Tools, equipments, irradiation facilities used for irradiation process shall have maintenance program and shall inspected to maintain efficiently usage.</p> <p>7.4 Chemical for washing or sanitizing, chemicals for maintenance shall be used under conditions of uses and kept separately for safety.</p> |
| 8 | Personnel and personal hygiene | <p>8.1 Staffs in irradiation building area shall not be infected from contagious disease or repugnant disease as prescribed in the Ministerial Laws.</p> <p>8.2 During irradiation process, all staffs which have direct contact to food, ingredients, or any surface which may have contact to food must be as the followings:</p> <p>8.2.1 Wear clean and suitable clothes or overcoat for work.</p> <p>8.2.2 Maintain a personal hygiene as necessary.</p> <p>8.3 The staffs who working in irradiation process shall be trained as the followings:</p> <p>8.3.1 Personal hygiene for general staffs</p> <p>8.3.2 The operation of irradiator and irradiation facilities for responsible staffs.</p> <p>8.3.3 Irradiation process control and dosimetry measurement for responsible staffs.</p> <p>8.4 Personnel not relevant to irradiation process shall follow to 8.1 - 8.2 when in irradiation area.</p> |

Annex 2

Attachment to the Notification of the Ministry of Public Health Re: Irradiated Food

Table: the maximum absorbed dose for the purpose of irradiation

| No. | Purpose of Irradiation | Maximum Absorbed Dose (Kilogray) |
|-----|--|-------------------------------------|
| 1 | To prevent sprouts of roots and tubers | 1 |
| 2 | To slow down ripeness | 2 |
| 3 | To control insect disinfestation | 2 |
| 4 | To decrease the amount of parasite | 4 |
| 5 | To prolong shelf life | 7 |
| 6 | To decrease the amount of microorganisms and pathogens | 10 |

Annex 3

Attachment to the Notification of the Ministry of Public Health Re: Irradiated Food

The food irradiation symbol



The symbol is a green bold edged circle. The edge of the upper half circle is divided equally into four fragments by five equal spaces. There is a one small green bold circle located in the upper half of inner circle. Whereas in the lower half of inner circle contains two separate green ellipses and each has one end connecting to the other.